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WITH DR. MEDLAW

Just about everyone who works at our family practice office (PAs, an RN, and clerical staff) is also a patient there. Needless to say, many of them are accessing their own records. I have talked to my partners about this because I am really concerned that we would be hit hard about this in a HIPAA investigation, but they said that it is fine because people are only looking at their own records, which they have a right to do. Are they correct, or am I?

You are.

A patient has the right to see their records but could not just go to the receptionist's desk and start downloading them. The same applies if they happen to work at the practice. There are proper procedures to follow.

The real issue is that this conduct is a red flag for HIPAA laxity at your practice if you are ever investigated, even for another reason, because it shows that you are treating records as an open access matter to all staff, including non-medical staff, which is an invitation to improper use. When records access is unregulated, it is frankly inevitable that there will eventually be privacy violations, such as looking up the records of someone the staff member has a personal question about.

When a staff member wants their results, have them submit a request just like any other patient would or simply ask their treating practitioner to check for them. Include this as a set policy in your office's employee regulations that can be proffered to the OCR as proof that you deal with this properly if you are investigated or used as evidence in a lawsuit for a privacy breach under state confidentiality law.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney. It originally appeared on SERMO, which retains all rights to it.



"I use so much alcohol-based hand sanitizer, my hands had to join a 12-step program!"

REN: A Novel Approach to Migraine Treatment



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Evidence suggests that pharmacologic agents often used to treat migraine may at times be ineffective, poorly tolerated, contraindicated, and—if used too frequently—can cause possible medication overuse headache, migraine chronification, and notable medical complications. A significant unmet need exists for effective and well-tolerated non-pharmacologic acute migraine therapy, according to Alan M. Rapoport, MD.

Studies have found external trigeminal nerve stimulation, non-invasive vagus nerve stimulation, and single-pulse transcranial magnetic stimulation to be safe and well-tolerated, non-invasive neuromodulation approaches. However, "they only work for up to 60% to 70% of patients," says Dr. Rapoport, with efficacies that are at times inferior to those reported for migraine-specific pharmacologic treatments.

A Novel Approach

A novel alternative to pharmacologic and the above-mentioned non-invasive neuromodulation approaches to acute migraine treatment may be found in the use of remote electrical

neuromodulation (REN). With REN, the upper arm peripheral nerves are stimulated to induce conditioned pain modulation, which Dr. Rapoport and colleagues explain as "a descending endogenous analgesic mechanism caused by subthreshold conditioning stimulation that inhibits pain in remote body regions. REN presumably activates descending inhibition pathways that travel through the periaqueductal gray (PAG) and in the rostral ventromedial medulla (RVM) and involve the release of the neurotransmitters serotonin and noradrenalin; they inhibit incoming messages of pain in the trigeminal cervical complex (TCC) that occur during a migraine headache attack."

A newly FDA-approved and available REN device (Nerivio; Theranica) is a wireless, wearable, battery-operated stimulation unit controlled by the patient through a smartphone app. Applied to the lateral upper arm for 45 minutes, the device mainly stimulates small skin nerves through a proprietary electrical signal comprising a modulated symmetrical biphasic square pulse with a modulated frequency of 100-120 Hz, pulse width of 400 μ s, and up to 40 mA output current (adjusted by the patient). In contrast with other neuromodulation treatments for migraine, the REN device uses upper arm

stimulation to produce global pain inhibition, allowing patients to continue with daily activities while it decreases migraine pain.

Data Thus Far

A pilot study, a pivotal study, and exploratory within-subject post hoc analyses thus far "show that the REN device works as well as existing treatments with almost no side effects," says Dr. Rapoport. The pilot study found that treatment with the REN device helped achieve significantly reduced headache pain when compared with a sham device and had the greatest effects when applied within the first 20 minutes from migraine attack onset and used for 45 minutes.

The pivotal study found a statistically significant, clinically important benefit of REN when compared with sham treatment in adults randomized to either treatment for 4-6 weeks. "Pain freedom at 2 hours was 37%," explains Dr. Rapoport (Figure). "Separate research shows this to be comparable with triptans. Pain relief at 2 hours was 67%, which is better than with many triptans." Pain freedom and pain relief rates at 2 hours with the sham device were 18% and 39%, respectively. Most bothersome symptom relief rates at 2 hours were 46% for REN and 22% for sham.

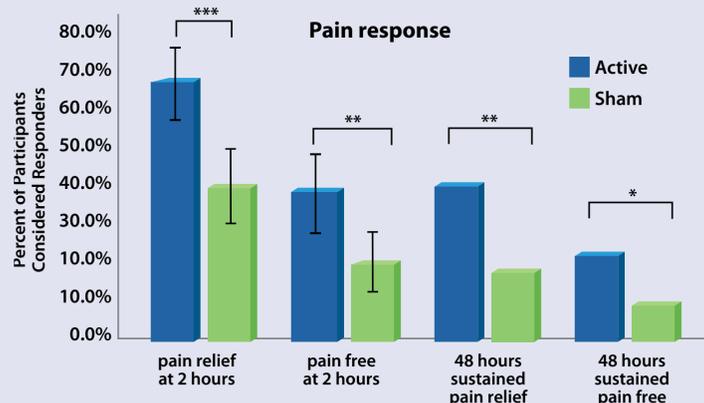
Exploratory within-subject post hoc analyses were performed on a subgroup of pivotal study participants who treated at least 1 attack with the active REN device and reported pain intensity at 2 hours posttreatment. "Each patient used usual care for 1 month before entering the double-blind study," notes Dr. Rapoport. "Upon comparing their response to REN with that of any usual care, REN was found to be more effective. When compared with migraine-specific medications only, REN treatment was found to be just as effective."

Looking Ahead

Trials are underway to study REN in more severe chronic migraine, with encouraging early results, according to Dr. Rapoport. "Future studies may also assess REN as a treatment for cluster headache, medication overuse headache, migraine with vertigo, and menstrual-related migraine," he adds, "as well as for preventive treatment of migraine. For now, REN is a promising new treatment for patients with migraine."

Figure Efficacy of Remote Electrical Neuromodulation

The figure below depicts pain response at 2- and 48-hours post-treatment. The error bars represent 95% confidence intervals.



***P < .001, **P < .005, *P < .05 (adapted with permission from Yarnitsky, et al14).

Source: Adapted from: Yarnitsky, et al. *Neurology*. 2017;88:1250-1255.

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Doctors and the Culture of Permission

Recently, Richard Smith, editor of *BMJ*, called out *NEJM* for failing to publish critical letters. His post in the *BMJ* blog network calls out *NEJM* as elitist. If electronic space is unlimited, he asks, why limit letters?

Good point. But why assume that conversation is controlled by *NEJM*? This is a great illustration of what I have come to call medicine's culture of permission.

As physicians, we've been raised to seek approval before approaching the microphone. For hundreds of years, you could only say something if someone gave you permission. It used to be that the only place we could share ideas was in a medical journal or from the podium of a national meeting. Our ideas were required to pass through someone's filter.

The angry scientists cited by Smith are of a generation when someone else decided if their ideas were worthy of discussion. They are a generation trained to contain what they think and believe. They are the medical generation of information isolation. Our culture of permission has bred a generation of obsequious followers.

When I think about my peers, I think about the remarkable mindshare that exists. Each is unique and brilliant in the way they think and see the world. Each sees disease and the human condition differently. They carry stories and experiences that can ease minds and save lives. But their brilliance and wisdom is stored away deep inside. They are human silos of unique experience and perspective.

But the way the world communicates and creates ideas is changing. The barrier to publish is effectively non-existent. The democratization of media has given every physician and scientist a platform to the world. But, somehow, we still believe that *NEJM* is running the show. The assumption here is that the only place for dialog and publication is within the boundaries of a paywall-controlled platform.

The problem here is not the antiquated ways of *NEJM*, but the dated, permission-based thinking of the medical public. ■

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External Trigeminal Nerve Stimulation for VM



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Despite being the most common neurologic cause of vertigo in adults, no FDA-approved treatments are available for vestibular migraine (VM), and few studies have assessed possibly effective rescue treatments. "There is a tremendous need for research into acute vestibular migraine therapies," says Shin C. Beh, MD. "Furthermore, because many patients are sensitive to, or concerned about, potential adverse effects of medications, a drug-free and efficacious therapy for VM would be a significant breakthrough for patient care."

For a single-center, retrospective review published in the *Journal of Neurological Sciences*, Dr. Beh treated 19 patients who had acute VM attacks with 20 minutes of external trigeminal nerve stimulation (eTNS) between May 2018 and June 2019. Before and after treatment, participants graded the severity of their vertigo/headache using a 10-point visual analog scale, with 0 representing no vertigo/headache and 10 representing the worst imaginable vertigo/headache.

All patients reported improvements in vertigo severity, with a 61.3% mean improvement from 6.6 prior to eTNS to 2.7 after. Among participants who experienced headache during VM episodes, headache severity improved a mean of 77.2%, from 4.8 before eTNS to 1.4 following treatment. Some patients also experienced improvements in eye pressure, head pressure, and chronic facial pain. No intolerable side effects of eTNS were reported.

"The most likely explanation for the effects of eTNS on VM is the close link between the trigeminal and vestibular systems in many brainstem nuclei," explains Dr. Beh. I believe that eTNS alters trigeminal input (via the ophthalmic branch of the trigeminal) to these brainstem nuclei and stops the neural activity responsible for generating a VM attack. It is important to emphasize that VM is a treatable condition and that novel, drug-free, non-invasive, safe, and effective treatment options like eTNS are available. My small, unblinded study provides clinicians with evidence of another potential option to help their patients with VM and supports the link between vertigo and migraine pathophysiology in the disorder." ■

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